



APR 27 2004

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(use as many sheets as necessary)

She

1

of

6

Complete if Known	
Application Number	10/759,099
Filing Date	January 20, 2004
First Named Inventor	O'Leary et al.
Art Unit	1642 1637
Examiner Name	CACAMITA
Attorney Docket Number	AFIP 03-16 01

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
Nel	A	US-4,708,933	11-24-1987	HUANG, LEAF et al.	
	B	US-4,957,735	09-18-1990	HUANG, LEAF	
	C	US-5,227,170	07-13-1993	SULLIVAN, Sean	
	D	US-5,389,523	02-14-1995	PLANT, Anne L. et al.	
	E	US-5,494,803	01-27-1996	CARBONELL, RUBEN G. et al.	
	F	US-5,604,099	02-18-1997	ERLICH, HENRY A. et al.	
	G	US-5,656,493	08-12-1997	MULLIS, Kary B. et al.	
	H	US-5,665,539	09-09-1997	SANO, Takeshi et al.	
	I	US-5,716,784	02-10-1998	DI CESARE, Joseph L.	
	J	US-5,776,487	07-07-1998	MAXFIELD WILSON, Nancy et al.	
	K	US-5,858,665	01-12-1999	HEPP, Jozef et al.	
	L	US-5,922,553	07-13-1999	EBERWINE, James et al.	
	M	US-6,013,442	01-11-2000	KOLESAR, Jill M. et al.	
	N	US-6,261,771 B1	07-17-2001	BOHANNON, Robert C.	
	O	US-6,268,148 B1	07-31-2001	BARANY, Francis et al.	
	P	US-6,326,147 B1	12-04-2001	OLDHAM, Mark F. et al.	
	Q	US-6,461,817 B1	10-08-2002	ALLAND, David et al.	
	R	US-20030104506 A1	06-05-2003	DURST, Richard A. et al.	
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

**Examiner
Signature**

John G. Clegg

Date Considered

08/22/7006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not relied upon.

considered. Include copy of this form with next communication to applicant.
In notice of unique status designation, attach copy of Form 250-10, "Grant of MPTO Status,"

Applicant's unique citation designation number (optional). *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the

Applicant is requested to check either the English document or the German document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of

6

Complete if Known

Application Number	10/759,099
Filing Date	January 20, 2004
First Named Inventor	O'Leary et al.
Group Art Unit	1641 1637
Examiner Name	PALAMERA
Attorney Docket Number	AFIP 03-16 01

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
HL	AA	ALFONTA, LITAL et al., "Liposomes Labeled with Biotin and Horseradish Peroxidase: A Probe for the Enhanced Application of Antigen-Antibody or Oligonucleotide-DNA Sensing Processes by the Precipitation of an Insoluble Product on Electrodes", Analytical Chemistry, January 1, 2001, Vol 73, No.1, pgs. 91-102.
HL	BB	BAILEY, AUSTIN L. et al., "Efficient Enapsulation of DNA Plasmids in Small Neutral Liposomes Induced by Ethanol and Calcium", Biochimica et Biophysica Acta, 2000, Vol. 1468, pgs. 239-252.
HL	CC	BRIDGES, MICHAEL AL. et al., "Fluorometric Determination of Nanogram Quantities of Protein in Small Samples: Application to Calcium-transport Adenosine Triphosphatase", Cli. Chim Acta 157, pgs. 73-79.
HL	DD	CHAURAND PIERRE, et al., "Direct Profiling of Proteins in Biological Tissue Sections by MALDI Mass Spectrometry", Analytical Chemistry, December 1, 1999, Vol. 71, No. 23, pgs. 5263-5270.
HL	EE	CHENG, SIEW BANG et al., "Development of a Multichannel Microfluidic Analysis System Employing Affinity Capillary Electrophoresis for Immunoassay", Analytical Chemistry, April 1, 2001, Vol. 73, No. 7, pgs. 1472-1479.
HL	FF	CROWTHER, JOHN R., "ELISA, Theory and Practice" Meth. Mol. Biol., Vol. 42, Humana Press, Totowa, NJ., pgs. 35-62.
HL	GG	DENY, YUZHONG et al., "Chip-based Quantitative Capillary Electrophoresis/mass Spectrometry Determination of Drugs in Human Plasma", Analytical Chemistry Vol. 73, pgs. 1432-1439.
HL	HH	DEO, SAPNA K., et al., "An Immunoassay for Leu-enkephalin Based on a C-terminal Aequorin-peptide fusion", Analytical Chemistry, Vol. 73, pgs. 1903-1908.
HL	II	DOUCETTE, ALAN et al., "Protein Concentration and Enzyme Digestion on Microbeads of MALDI-TOF Peptide Mass Mapping of Proteins for Dilute Solutions", Analytical Chemistry, July 15, 2000, Vol. 72, No. 1, pgs. 3355-3362.
HL	JJ	DOYLE, J. M., et al., "Electrochemical Sensors in Immunological Analysis", Plenum Press, New York, NY, pgs. 87-102.

Examiner Signature

Date Considered

08/22/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/759,099
Sheet	3	of	6	Filing Date	January 20, 2004
				First Named Inventor	O'Leary et al.
				Group Art Unit	1641- 1637
				Examiner Name	CALAMITA
				Attorney Docket Number	AFIP 03-16 01

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (In CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
KK	EGELHOFER, V., Improvements protein identification by MALDI-TOF-MS Peptide mapping", Analytical Chemistry, July 1, 2000, Vol. 72, No. 13, pgs. 2741-2750.				
LL	FELTUS, AGATHA et al., "Detection of Biotin in Individual Sea Urchin Oocytes Using a Bioluminescence Binding Assay", Analytical Chemistry, April 1, 2001, Vol. 73, No. 7, pgs. 1403-1407.				
MM	FRALEY, ROBERT et al., "Introduction of Liposome-encapsulated SV40 DNA into Cells", The Journal of Biological Chemistry, November 10, 1980, Vol. 255, No. 21, pgs. 10431-10453.				
NN	FRY, DAVID W., et al., "Rapid Separation of Low Molecular Weight Solutes from Liposomes Without Dilution", Academic Press Inc., 1978, pgs. 809-815.				
OO	GOMORI, G., "A Modification of the Colorimetric Phosphorus Determination for Use with the Photoelectric Colorimeter", The Journal of Laboratory and Clinical Medicine, pgs. 955-960.				
PP	HEATH, T.D., et al., "Covalent Attachment of Immunoglobulins to Liposomes Via Glycosphingolipids", Biochimica et Biophysica Acta, 1981, Vol. 640, pgs. 65-81.				
QQ	HOPE, M. J., et al., "Production of Large Unilamellar Vesicles by a Rapid Extrusion Procedure. Characterization of Size Distribution, Trapped Volume and Ability to Maintain a Membrane Potential", Biochimica et Biophysica Acta, 1985, Vol. 812, pgs. 55-65.				
RR	HUANG, CHING-HSIEN, "Studies ofn Phosphatidylcholine Vesicles. Formation and Physical Characteristics", Biochemistry, January 1969, Vol. 8, No. 1, pgs. 344-347.				
SS	JONES, VIVIAN W. et al., "Microminiaturized Immunoassays Using Atomic Force Microscopy and Compositionally Patterned Antigen Arrays", Analytical Chemistry, April 1, 1998, Vol. 70, No. 7, pgs. 1233-1241.				
TT	KUNG, VIOLA T. et al., "Synthesis of Carboxyacyl Derivatives of Phosphatidylethanolamine and Use as an Efficient Method for Conjugation of Protein to Liposomes", Biochimica et Biophysica Acta, 1986, Vol. 862, pgs. 435-439.				
UU	LOYTER, A. et al., "Fusion-Mediated Injection of SV40-DNA. Introduction of SV40-DNA into Tissue Culture Cells by the Use of DNA-Loaded Reconstituted Sendai Virus Envelopes", Experimental Cell Research, 1983, 143, pgs. 415-425.				

Examiner Signature	<i>John H. Chito</i>	Date Considered	08/21/2006
--------------------	----------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
				Application Number	10/759,099
				Filing Date	January 20, 2004
				First Named Inventor	O'Leary et al.
				Group Art Unit	1644-1637
				Examiner Name	CHALAMITA
Sheet	4	of	6	Attorney Docket Number	AFIP 03-16 01

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
HOL	VV	MARTIN, FRANCIS J. et al., "Covalent Attachment of Proteins to Liposomes" in "Liposomes: a Practical Approach" (New, R.R.C., ed.) Oxford University Press, New York, NY, pgs. 163-182.		1 ²
	WW	MASON, J. T. et al., "Hydrodynamic Analysis of Egg Phosphatidylcholine Vesicles", Annals of the New York Academy of Sciences, June 19, 1978, Vol. 308, pgs. 29-49.		
	XX	MONROE, D., "Immunoassay Technology" (pal. S.B., ed.) Walter de Gruyter Co. Berlin, NY, pgs. 167-187.		
	YY	NAM, JWA-MIN et al., "Nanoparticle-Based Bio-Bar Codes for the Ultrasensitive Detection of Proteins", Science, September 26, 2003, Vol. 301, pgs. 1884-1886.		
	ZZ	NIEMEYER, CHRISTOF M. et al., "Fluorometric Polymerase Chain Reaction (PCR) Enzyme-Linked Immunosorbent Assay for Quantification of Immuno-PCR Products in Microplates", Analytical Biochemistry, 1997, Vol. 246, pgs. 140-145.		
	AAA	NIEMEYER, CHRISTOF M. et al., "Self-Assembly of DNA-Streptavidin Nanostructures and Their Use as Reagents in Immuno-PCR", October 1999, Vol. 27, No. 23, pgs. 4553-4561.		
	BBB	NEW, R. R. C., "Characterization of Liposomes" in "Liposomes: A Practical Approach, Practical Approach", (New, R.R.C., ed.)Oxford University Press, New York, NY, 1990, pgs. 105-161.		
	CCC	O'LEARY, TIMOTHY J. et al., "Use of Semiquantitative PCR to Assess Onset and Treatment of Pneumocystis Carinii Infection in Rat Model", Journal of Clinical Microbiology, March 1995, Vol. 33, No. 3, pgs. 718-724.		
	DDD	PAYNE, NICHOLAS I. Et al., "Characterization of Proliposomes", Journal of Pharmaceutical Sciences, April 1986, Vol. 75, No. 4, pgs. 330-333.		
	EEE	QIN, QIU-PING et al., "Development of Highly Fluorescent Detection Reagents for the Construction of Ultrasensitive Immunoassays", Analytical Chemistry, April 1, 2001, Vol. 73, No. 7, pgs. 1521-1529.		
HOL	FFF	REID, ANN H. "Polymerase Chain Reaction" in "Advanced Laboratory Methods In Histology and Pathology", (mikel, U, ed.) American Registry of Pathology Publications Washington, DC, pgs. 77-110.		

Examiner Signature	<i>Holm et al.</i>	Date Considered	08/22/2006
--------------------	--------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Substitute for form 1449B/PTO				Complete if Known	
				Application Number	10/759,099
				Filing Date	January 20, 2004
				First Named Inventor	O'Leary et al.
				Group Art Unit	1644 1637
				Examiner Name	CALAMITA
Sheet	5	of	6	Attorney Docket Number	AFIP 03-16 01

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
<i>Hao</i>	GGG	Ruzicka, VIKTOR et al., "Immuno-PCR with a Commercially Available Avidin System", Science, April 30, 1993, Vol. 260, pgs. 698-699.	
	HHH	Sano, TAKESHI et al., "Immuno-PCR: Very Sensitive Antigen Detection by Means of Specific Antibody-DNA Conjugates", Science, October 2, 1992, Vol. 258, pgs. 120-122.	
	III	Sheng, ZONG-MEI et al., "Rapid Screening for KIT Mutations by Capillary Electrophoresis", Clinical Chemistry, 2001, Vol. 47, No. 7, pgs. 1325-1326.	
	JJJ	Singh, ANUP K. et al., "Gangliosides as Receptors for Biological Toxins: Development of Sensitive Fluorimmunoassays Using Ganglioside-Bearing Liposomes", Analytical Chemistry, December 15, 2000, Vol. 72, No. 24, pgs. 6019-6024.	
	KKK	Smith, IAN C. P., et al., "Phosphorus-31 NMR of Phospholipids in Membranes", Academic Press, Inc. 1984, pgs. 447-460.	
	LLL	Szoka, JR., FRANCIS et al., "Procedure for Preparation of Liposomes with Large Internal Aqueous Space and High Capture by Reverse-phase Evaporation", Proc. Natl. Acad. Sci., September 1978, Vol. 75, No. 9, pgs. 4194-4198.	
	MMM	Szoka, JR., FRANCIS et al., "Comparative Properties and Methods of Preparation of Lipid Vesicles (Liposomes)", Ann. Rev. Biophys. Bioeng., 1980, Vol. 9, pgs. 467-508.	
	NNN	Tanabe, TETSUYA et al., "Fluorescent Cyclodextrin Immobilized on a Cellulose Membrane as a Chemosensor System for Detecting Molecules", Analytical Chemistry, April 15, 2001, Vol. 73, No. 8, pgs. 1877-1880.	
	OOO	Wang, JOSEPH et al., "Capillary Electrophoresis Microchips for Separation and Detection of Organophosphate Nerve Agents", Analytical Chemistry, April 15, 2001, Vol. 73, No. 8, pgs. 1804-1808.	
	PPP	Wong, W. M. et al., "Genomic Sequence of a Sprague-Dawley rat β -globin gene", Nucleic Acids Research, 1988, Vol. 16, No. 5, pg. 2342-2348.	
<i>Hao</i>	QQQ	Wu, H. C. et al., "Detection of Clostridium Botulinum Neurotoxin in Type A Using Immuno-PCR", Letters in Applied Microbiology, 2001, Vol. 31, pgs. 321-325.	

Examiner Signature	<i>John H. Choi</i>	Date Considered	08/26/2006
--------------------	---------------------	-----------------	------------

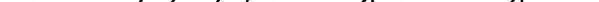
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/759,099
				Filing Date	January 20, 2004
				First Named Inventor	O'Leary et al.
				Group Art Unit	1641/1637
				Examiner Name	CACAMITA
Sheet	6	of	6	Attorney Docket Number	AFIP 03-16 01

Examiner Signature		Date Considered	08/01/2008
--------------------	---	-----------------	------------

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231